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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/483,337	01/14/2000	Eric T. Kool	220.00040101	8254

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[REDACTED] EXAMINER

CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
1623	(21)

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/483,337</b>	Applicant(s) <b>E. T. Kool</b>
	Examiner L. E. Crane	Group Art Unit 1623

- THE MAILING DATE of this communication appears on the cover sheet beneath the correspondence address -

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE --3-- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be filed after six months from the date of this communication.
- If the prior for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty days will be considered timely.
- If NO period for reply is specified above, such period shall ,by default, expire SIX (6) MONTHS from the date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 USC §133).

## Status

Responsive to communication(s) filed on -06/02/03 (Response & RCE) & 12/30/02 (Letter/Intv. Summary).  
 This action is **FINAL**.  
 Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

Claims --44-48, 50-54 & 56-60-- are pending in the application. Claims -[]- have been cancelled.  
 Of the above claims --[]-- are withdrawn from consideration.  
 Claims --[]-- is/are allowed.  
 Claims --44-48, 50-54 & 56-60-- are rejected.  
 Claim(s) --[]-- is/are objected to.  
 Claims --[]-- are subject to restriction or election requirement.

## Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
 The proposed drawings, filed on -12/20/02- are  approved  disapproved.  
 The drawing(s) filed on -[]- is/are objected to by the Examiner.  
 The specification is objected to by the Examiner.  
 The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119(a)-(d)

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).  
 All  Some \*  None of the CERTIFIED copies of the priority documents have been received.  
 received in Application No. (Series Code/Serial Number) -[]-.  
 received in the national stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* Certified copies not received: -[]-.

## Attachment(s)

<input type="checkbox"/> Information Disclosure Statement(s), PTO-1449, Paper No(s). <u>-[]-</u>	<input type="checkbox"/> Interview Summary, PTO-413
<input type="checkbox"/> Notice of Reference(s) Cited, PTO-892	<input type="checkbox"/> Notice of Informal Patent Application, PTO-152
<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review, PTO-948	<input type="checkbox"/> Other: <u>-[]-</u>

Art Unit 1623

No claims have been cancelled, no claims have been added, and no claims have been amended as per the Response filed June 2, 2003. No additional Supplemental Information Disclosure Statements (IDSs) have been received. A Letter was filed by applicant's representative by FAX on 5 December 30, 2002 and constitutes a rebuttal to examiner's grounds of rejection found in Paper No. 16.

Claims 44-48, 50-54 and 58-60 remain in the case.

Claims 44-48, 50-54 and 56-60 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly 10 point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 44, 50 and 56 at lines 8, 9 and 10, lines 12, 14, 17, 18, 19 and 20 and lines 7, 8 and 9, respectively, the term "comprising" renders the metes and bounds of the claim indefinite, particularly 15 because said term refers to chemically modified starting materials and products and by such reference implies the absence of a complete description of the structural features of said chemically modified starting materials and products. Said term, as a synonym of including, begs the question -- Including what else?--

20 Applicant's arguments filed June 2, 2003 have been fully considered but they are not persuasive.

Applicant alleges that the above rejection is not understood because "it is not clear as to which part of the claim the Examiner is applying the rejection." Examiner has amended the rejection to more particularly 25 point out why the rejection was made, more particularly point out the term to which it is deemed to apply, and the lines in which said term

Art Unit 1623

appears in the noted claims. Applicant also argues that "comprising" is an acceptable transitional term. Examiner agrees in part, but in rebuttal argues that this term does not apply to claims or portions of claims directed to chemical structures because said term may be read to imply 5 an incomplete description of the chemical structure; e.g. the claim -- A compound comprising ethanol. -- reads on potable distilled liquors and/or on chemical analogues of ethanol whereas the claim -- A compound having the formula CH<sub>3</sub>-CH<sub>2</sub>-OH-- is directed only to the compound ethanol and may not be read to include mixtures of ethanol 10 with other substances or to compounds which are structurally related to ethanol.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same 15 claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow 20 language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex 25 parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 44, 50 and 56 recite the broad recitations "comprises" and "comprising," and the claim also recites "selected from the group consisting of" which is the narrower statement of the range/limitation.

Art Unit 1623

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

5 (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

10 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

Claims 44-48, 50-54 and 56-60 are rejected under 35 U.S.C. §102(b) as being anticipated by Northwestern University '699 (PTO-1449 ref. AM).

15 Applicant is referred to the abstract at page 1, pages 13 and 17 and Figure 2 wherein the instant claimed invention has been anticipated.

Applicant's arguments filed June 2, 2003 have been fully considered but they are not persuasive.

20 Applicant is claiming the "autoligation" process of Letsinger et al. which is entirely disclosed by the instant reference. Applicant argues that all of the detailed limitations of the instant claims are not found in the prior art. Examiner respectfully disagrees, noting that applicant is doing nothing more or less than the process of the '699 reference, which reference claims autoligating oligonucleotides probe fragments which are not limited as to the length of the ligating oligonucleotide.

Art Unit 1623

Claims **44-48, 50-54 and 56-60** are rejected under 35 U.S.C. §102(b) as being anticipated by Letsinger et al. '943 (PTO-1449 ref. AC).

Applicant is referred to claims **1 and 5** at columns 15-16 wherein  
5 the instant claimed process is anticipated in its entirety.

Claims **44-48, 50-54 and 56-60** are rejected under 35 U.S.C. §102(b) as being anticipated by Gryaznov et al. '903 (PTO-1449 ref. AB).

Applicant is referred to the abstract, to claims **1-13**, and to column  
10 10 at lines 3-4 which together anticipate the instant claimed process.

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

15 "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made."

Claims **44-48, 50-54 and 56-60** are rejected under 35 U.S.C.  
20 §103(a) as being unpatentable over Northwestern University '699 (PTO-1449 ref. AM).

The instant claims are directed to a process of autoligation wherein  
25 autoligating oligonucleotides bind to a target solid-supported linked oligonucleotide target and when hybridization takes place under relatively non-stringent conditions the autoligating probes which hybridize in a sequence specific manner with the target undergo chemical autoligation forming a new oligonucleotide which is then

Art Unit 1623

subsequently detected as an indication of the presence of the target sequence.

**Northwestern University '699** in claims *1 and 5* discloses the autoligation process claimed herein.

5       **Northwestern University '699** does not expressly disclose the particular target oligonucleotide or details of the oligonucleotide sequence to be autoligated to.

10      It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the instant disclosed process to any solid-supported target including the targets taught by the instant claims. Any variations required to achieve a working test process with a different target sequence are deemed to have been within the purview of the ordinary practitioner seeking to optimize the prior art process, in the absence of a clearly convincing showing of unexpected results.

15      Therefore, the instant claimed hybridization-based method of oligonucleotide sequence detection would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

20      Examiner notes applicant's request for an interview. Examiner agrees that this would be a good idea and notes analogy with a similar situation in an earlier prosecution wherein prior art made it impossible for instant examiner to allow claims which failed to specify sequences in an application directed to DNA testing issued to Jeffreys (US 5,413,908). Additionally, examiner finds that the wording of claim 54  
25 is so convoluted and verbose that it is very difficult to understand the subject matter being claimed. Therefore, if an interview is to occur, examiner suggests that applicant's representative and/or applicant

Art Unit 1623

should come to any personal interview prepared to provide a detailed description with chemical formulas of the reactants including an easily understood visualization of how they are combined in the claimed testing process. Said visualization would be expected to show how the process steps in claims **44, 54 and 56** are intended to be understood, and how these processes are distinguishable from **Northwestern University '699** in words-only claims.

Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are **(703) 308-4556** and **703-305-3592**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **703-308-4639**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at **(703)-308-4624**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **703-308-1235**.

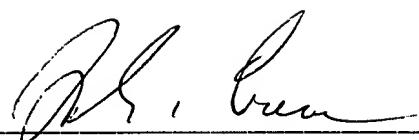
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Art Unit 1623

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**06/15/03**

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